

Docket No.: TIBO-0029
Application No.: 09/836,477
Response to Office Action Dated: May 13, 2004

PATENT

REMARKS

In the Office Communication dated May 13, 2004, claims 1 to 42 were subject to restriction under 35 U.S.C. § 121, as follows:

I. **Claims 1-27 and 39-42** drawn to a method and computer program of determining a phenotype of a biological sample comprising obtaining a sequence, identifying a mutation, searching a relational database, obtaining a phenotype and determining a phenotype, classified in Class 702, subclass 20;

II. **Claims 28-32**, drawn to a method, business method, and computer program for determining a phenotype of a biological sample comprising obtaining a sequence, searching a relational database, obtaining a database phenotype, and determining a phenotype, classified in Class 702, subclass 20.

III. **Claims 33-34**, drawn to a method of assessing effectiveness of a therapy on a patient, classified in Class 702, subclass 20.

IV. **Claim 35**, drawn to a method of optimizing therapy for a patient, classified in Class 702, subclass 20.

V. **Claim 36**, drawn to a method of designing a therapy for a patient, classified in Class 702, subclass 20.

VI. **Claims 37-38**, drawn to a business method, classified in Class 705, subclass 2.

It is asserted that the invention of Group I requires an additional step of identifying a mutation pattern for determining a phenotype, that is not a critical limitation of the invention of Group II. It is further asserted that the inventions of Group I and Group III are unrelated, as the Group III step of assessing effectiveness of a therapy is not included in the invention of Group I. It is asserted that the inventions of Group I and Group IV are unrelated, as the Group IV step of optimizing therapy is not a limitation in the steps of Group I. It is further asserted that the inventions of Group I and Group V are unrelated, as the Group V step of designing a therapy for a patient is not included in the invention of Group I. It is asserted that the inventions of Group I and Group VI are unrelated, as Group VI is drawn to a business method, which is not a limitation of Group I.

It is further asserted that the inventions of Group II and Group III are unrelated as Group II is drawn to determining a phenotype and the Group III is drawn to assessing the effectiveness of a therapy. It is further asserted that the inventions of Group II and IV are unrelated as Group II is drawn to assessing phenotype and Group IV is drawn to optimizing therapy. It is asserted that the inventions of Group II and Group V are unrelated as the invention of Group II is drawn to determining phenotype and Group V is drawn to a method of designing a therapy, which include different inventive purposes and outcomes. It is further asserted that the inventions of Group II and Group VI are unrelated. It is asserted that Group VI is drawn to a business method which is not a limitation of Group II (method of determining phenotype).

It is asserted that the inventions of Group III and Group IV are unrelated as Group III is drawn to assessing the effectiveness of a therapy while Group IV is drawn to methods of optimizing a therapy, which do not encompass the same inventive purpose. It is further asserted that the inventions of Group III and Group V are unrelated. It is asserted that Group V includes a method of designing therapy which is not a limitation of Group III.

It is asserted that the inventions of Group III and Group VI are unrelated. Group VI includes a business method which is not a limitation of Group III. It is further asserted that the inventions of Group IV and Group V are unrelated as Group IV is drawn to a method of optimizing therapy while Group V is drawn to a method of designing a therapy which encompasses a different inventive purpose with different outcomes. It is also asserted that the

inventions of Group V and Group VI are unrelated. It is asserted that Group VI includes a business method which is not a limitation of the therapy design methods of Group V.

It is stated in the Office Communication that the various groups are directed to unrelated subject matter.

Applicants respectfully traverse the restriction requirement. According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 to § 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) to § 806.04(i), § 808.01(a), and § 808.02).

For purposes of the initial requirement, a serious burden may be *prima facie* shown if the examiner shows separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. In the subject application, the claims have been **restricted into 7 different groups**, however, these groups have only been **classified into two different classes**, namely Class 702 and Class 705. As the restriction requirement is currently drawn, *Applicants would be required to file more than 6 divisional applications to cover the subject matter of the original application*. It is respectfully submitted that this is unduly burdensome to the Applicants. At a minimum, Applicants respectfully request reconsideration with respect to a reduction in the number of groups from 7 to two. Applicants believe that Groups I and II are so closely related they should be rejoined into one group. Similarly, Groups II, IV and V are so closely related they should be rejoined into one group.

Thus, Applicants respectfully request reconsideration of the requirement for restriction, and in particular an indication that the requirement is only a provisional election for the purpose of carrying out the search. Nonetheless, to be fully responsive to the restriction requirement, Applicants elect *with traverse* to prosecute the claims of **Group I (claims 1-27 and 39-42)**.

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CONCLUSION

Applicants hereby elect, with traverse, Group I consisting of claims 1-27 and claims 39-42. Applicants reserve the right to pursue the subject matter of all non-elected claims in one or more related applications. Applicants respectfully request an early and favorable action.

The examiner may call the undersigned at 206.332.1380 if a telephonic interview is required.

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